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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,009	05/16/2001	Alexander Kozak	800.1012	2594

7590 01/06/2003

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485 Seventh Avenue 14th Floor  
New York, NY 10018

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n No.</b> 09/856,009	<b>Applicant(s)</b> KOZAK ET AL.	
	<b>Examin r</b> Sonya Wright	<b>Art Unit</b> 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on \_\_\_\_.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_ is/are objected to.

8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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### DETAILED ACTION

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Claims 1-33 are pending in this application.

#### ***Election/Restrictions***

Due to the numerous variables in the claims, R1, R2, D, X, and Z, and their widely divergent meanings, a precise listing of inventive groups can not be made. The following groups are exemplary:

Group I, claims 1-26, 28, and 29, drawn to compounds and compositions of formula I, and a method for treatment of a disease or disorder, wherein R1 is a saturated unsubstituted hydrocarbon chain having from 2 to 30 carbon atoms, R2 is H, and D is diclofenac, classified in various classes and subclasses.

Group II, claims 1-26, 28, and 29, drawn to compounds and compositions of formula I, and a method for treatment of a disease or disorder, wherein R1 is an unsaturated, unsubstituted hydrocarbon chain having from 2 to 30 carbon atoms, R2 is phospholipid head group, and D is indomethacin, classified in various classes and subclasses.

Group III, claim 27, drawn to drawn to a use for the manufacture of a medicament, wherein R1 is a saturated unsubstituted hydrocarbon chain having from 2 to 30 carbon atoms, R2 is H, and D is diclofenac, classified in various classes and subclasses.

Group IV, claim 27, drawn to a use for the manufacture of a medicament, wherein R1 is an unsaturated, unsubstituted hydrocarbon chain having from 2 to 30

carbon atoms, R2 is phospholipid head group, and D is indomethacin, classified in various classes and subclasses.

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Group V, claims 30-33 drawn to a process for the synthesis of compounds of the general formula I, wherein R1 is a saturated, unsubstituted hydrocarbon chain having from 2 to 30 carbon atoms, R2 is H, and D is naproxen, classified in various classes and subclasses.

Group VI, claims 30-33, drawn to a process for the synthesis of compounds of the general formula I, wherein R1 is a saturated unsubstituted hydrocarbon chain having from 2 to 30 carbon atoms, R2 is H, and D is diclofenac, classified in various classes and subclasses.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhaustive. It would be impossible to formulate a complete listing of groups under the time constraints, due to the sheer volume of subject matter instantly claimed. Therefore, Applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain nonsteroidal anti-inflammatory drugs covalently conjugated, via a bridging group, to a phospholipid, and the compounds contain R1, R2, D, X, and Z,

which does not define a contribution over the art. The variables are broadly defined, and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking a restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not

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communicate with applicant via Internet e-mail where sensitive data will be exchanged  
or where there exists a possibility that sensitive data could be identified unless there is  
of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by  
the applicant. See the Interim Internet Usage Policy published by the Patent and  
Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should  
be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

January 2, 2003



**ALAN L. ROTMAN**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**